

**NOTICE OF PROPOSED REGULATION ADOPTION**

**California Code of Regulations  
Title 17. – Public Health  
Division 4 - California Institute For Regenerative Medicine  
Chapter 5**

**Date: August 1, 2006**

**Deadline for Submission of Written Comment: September 25, 2006 – 5:00 p.m.**

**Hearing Date: None scheduled.**

**Subject Matter of Proposed Regulations: Grants Administration Policy for Academic and Non-Profit Institutions**

**Sections Affected:**

The proposed regulations adopt Chapter 5 and section 100500 of Title 17 of the California Code of Regulations.

**Authority:** Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

**Reference:** Sections 125290.30, subdivisions (e) and (i), 125290.45, subdivision (a)(2), 125290.50, subdivision (f), 125290.60, 125292.10, Health and Safety Code.

**Informative Digest/Policy Statement Overview:**

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in early 2005 with the passage of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides \$3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens’ Oversight Committee (“ICOC”) is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The Act charges the ICOC with developing standards and criteria to make grant awards and to develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, the Scientific and Medical Research Funding Working Group has developed a document titled “CIRM Grants Administration Policy for Academic and Non-Profit

Institutions.” This policy serves to guide grant recipients on their responsibilities as CIRM grantees. Principal investigators, program directors, and organizational officials with grants management responsibilities may refer to pertinent sections for answers to questions that arise concerning the administration of the grants. By accepting a CIRM grant award, the grantee is agreeing to comply with the provisions set forth in the policy for the entire project period of the grant.

In addition to a section broadly defining the terms used in the policy and identifying key personnel on grantee organization staff and their responsibilities, the document sets forth the rules governing the grant application and review process, including sections addressing eligibility, application submission, application review, criteria for review of applications, appeals of grant decisions, procedures after approval, and the public access to public records.

Another key area addressed in the policy concerns pre- and post-grant award responsibilities and issues. For instance, the policy will address apportionment of liability for research, public policy requirements concerning use of human tissue, animal subjects and biosafety, as well as sharing of intellectual property, preference for California suppliers and a “just-in-time” policy describing the process for preparing for a grant award.

The policy describes the requirements for award acceptance and various provisions addressing the payment and use of grants funds. For instance, the policy describes allowable and unallowable project costs and activities, as well as permissible and impermissible facilities costs. The policy describes the policies and procedures applicable for prior approval requirements for programmatic and other changes, the process for appropriate documentation of use of CIRM funds, reporting requirements and the misuse of funds. The policy also addresses the consequences for failure of compliance with the terms and conditions of CIRM grant awards.

The final primary section of the policy address issues pertinent to training grants made by the CIRM, including the criteria for review of training grant applications, degree requirements for trainees, allowable costs and activities, and reporting requirements for training grant recipients.

### **Technical, Theoretical or Empirical Studies, Reports or Documents:**

There are many sources that provide helpful information about the administration of CIRM-supported grants or that are relevant to the regulation. Below is a compendium of websites that contains information and useful reports relating to intellectual property, data and materials sharing, and licensing trends. Some components of the proposed regulations were developed using guidelines and regulations contained in these documents:

**A. General Interest Sites:**

CIRM – <http://www.cirm.ca.gov/>  
National Academy of Sciences – <http://www.nas.edu/>  
National Institutes of Health – <http://www.nih.gov>  
Office for Human Research Protections, DHHS – [www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)  
Office of Laboratory Animal Welfare – <http://grants1.nih.gov/grants/olaw>  
Office of Research Integrity, DHHS – [www.ori.dhhs.gov](http://www.ori.dhhs.gov)  
U.S. Food and Drug Administration – [www.fda.gov](http://www.fda.gov)

**B. Grant Administration Policies:**

American Heart Association  
American Cancer Society  
Special Research Programs at UCOP  
Juvenile Diabetes Research Foundation  
National Institutes of Health – December, 2003  
Susan B. Koman Breast Cancer Foundation  
National Academy of Sciences  
Florida Department of Health

**C. Other Documents and Sources:**

Public Health Service Policies on Research Misconduct – 42 CFR Part 93  
Responsibility of Applicants for Promoting Objectivity in Research for which  
PHS Funding is Sought (10/20/00) – 42 CFR Part 50, Subpart F  
Guide for Care and Use of Laboratory Animals (1/2/96) – NAS  
Protection of Human Subjects – 45 CFR Part 46  
Animal Welfare Act – 9 CFR Ch. 1

**D. Public Input:**

Public input received at six public meetings conducted by the ICOC and Scientific and Medical Research Working Group, on November 28, 2005, December 6, 2005, and February 10, March 14, April 6 and June 2, 2006.

Copies of the documents referenced above may be found at the internet site listed. In addition, these documents are also available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in Section “D” are available on CIRM’s website, [www.cirm.ca.gov](http://www.cirm.ca.gov) under the “Meetings Transcripts” link.

**Submittal of Comments:**

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later

than 5:00 p.m. on September 25, 2006. Comments regarding this proposed action may also be transmitted via e-mail to [gapcomments@cirm.ca.gov](mailto:gapcomments@cirm.ca.gov) or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than September 11, 2006.

**Effect on Small Business:**

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulations implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulations are not expected to adversely impact small business as defined in Government Code section 11342.610.

**Impact on Local Agencies or School Districts:**

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

**Costs or Savings to State Agencies:**

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

**Effect on Federal Funding to the State:**

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory actions.

**Effect on Housing Costs:**

CIRM has made an initial determination that the proposed actions will have no effect on housing costs.

**Significant Statewide Adverse Economic Impact Directly Affecting Businesses:**

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

**Cost Impacts on Representative Private Persons or Businesses:**

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

**Impact on the Creation, Elimination, or Expansion of Jobs:**

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

**Consideration of Alternatives:**

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

**Availability of Statement of Reasons and Text of Proposed Regulations:**

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

**Availability of Changed or Modified Text:**

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

**Agency Contact:**

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher, Interim Counsel  
California Institute For Regenerative Medicine  
210 King Street  
San Francisco, CA 94107  
(415) 396-9136

Questions on the substance of the proposed regulatory action may be directed to:

Gilberto R. Sambrano, Ph.D.  
Scientific Review Officer  
California Institute For Regenerative Medicine  
(415) 396-9103

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, [www.cirm.ca.gov](http://www.cirm.ca.gov).

**Availability of Final Statement of Reasons:**

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at [www.cirm.ca.gov](http://www.cirm.ca.gov).